

AMENDMENT UNDER 37 C.F.R. § 1.116
U.S. Appln. No. 09/445,963

REMARKS

Review and reconsideration on the merits are requested.

The prior art relied upon is referred to using the following terminology: Kajiwara; Jichlinski; Jaffe, Kennedy.

Claims 5 and 6 are canceled. The remaining claims, claims 7-11, are amended.

Applicants now turn to the rejections.

With respect to the rejection of claim 7, 9 and 11 under 35 U.S.C. § 112, second paragraph, “or pharmaceutically” is canceled from these claims, which it is believed avoids the rejection.

Withdrawal is requested.

With respect to the rejection of claims 5 and 6, this rejection is mooted by canceling these claims.

Claims 8 and 9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jichlinski in view of Jaffe.

Claims 10 and 11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kajiwara and Kennedy. Applicants believe they have understood this rejection as presented in Paragraph 10 of the Action, since at the top of page 4 of the Action, the teachings of Kajiwara and Kennedy are combined, but if they have misunderstood this rejection and the Examiner means to pose an anticipation rejection, the Examiner is requested to call Counsel of record at the later given telephone exchange.

The above rejections are respectfully traversed.

AMENDMENT UNDER 37 C.F.R. § 1.116
U.S. Appln. No. 09/445,963

Turning first to the rejection of claims 8 and 9 over Jichlinski and Jaffe, the present invention and Jichlinski both use the phenomenon that ALA will accumulate in a malignant tumor. However, neither Jichlinski nor Jaffe disclose nor suggest that the malignant tumor can be diagnosed with NMR such as MRI or the like by using ALA of a specific isotope or derivative form as claimed herein. Accordingly, it is not believed that one of ordinary skill in the art would be led to the present invention as claimed from the teaching of Jichlinski and Jaffe.

In the field of structural analysis and metabolic studies, quite often compounds are structurally analyzed using NMR by introducing a stable isotope into the compounds. This is a general technique; see, in this regard, Kajiwara and Jaffe.

However, in such a technique, the reactant must be separated and purified and the compound to be examined must be subjected to NMR spectral measurement. Even if one were to combine techniques in the above fields of structural analysis and metabolic studies with Jichlinski disclosing that porphyrins accumulate in tumors with the administration of ALA, one of ordinary skill in the art would not be led to apply art regarding structural analysis and metabolic studies to tumor diagnosis as is the case of the present invention.

The present invention and Jichlinski both also relate to treatment of malignant tumors. However, in the present invention, the position of the malignant tumor can be more easily identified using NMR such as MRI or the like as compared to Jichlinski. Therefore, a more effective treatment is obtained by a combination with laser treatment or the like in accordance with the present invention.

AMENDMENT UNDER 37 C.F.R. § 1.116
U.S. Appln. No. 09/445,963

With respect to the rejection of claims 10 and 11, neither Kajiwara nor Kennedy disclose a diagnosis method as set forth in claim 8. Accordingly, claim 10 is amended by including the "detecting... NMR" language of claim 8. With respect to the "selectively killing the detected malignant tumors" language, this is based on page 18, line 9 in the specification.

Applicants position on the rejection over Kajiwara and Kennedy is traversed for the reasons set forth regarding the rejection of claims 8 and 9.

Withdrawal of all rejections is requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,



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APPENDIX
VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 5 and 6 are canceled.

The claims are amended as follows:

7. (Amended) A composition comprising a compound or derivative thereof in which at least one carbon atom of 5-aminolevulinic acid is a carbon isotope and/or a nitrogen atom in its amino group is a nitrogen isotope, and where said derivative is an ester, amide, salt, hydrate or solvate of the compound, and a diagnostically [or pharmaceutically] acceptable carrier.

8. (Amended) A method for detecting malignant tumors, which method comprises administering a tumor detecting effective amount to a host in need of tumor detection of a compound or derivative thereof in which at least one carbon atom of 5-aminolevulinic acid is a carbon isotope and/or a nitrogen atom in its amino group is a nitrogen isotope, and where said derivative is an ester, amide, salt, hydrate or solvate of said compound and

detecting the malignant tumors using NMR.

9. (Amended) The method of claim 8 wherein said compound is used in combination with a diagnostically [or pharmaceutically] acceptable carrier.

10. (Amended) A method for photokinetically treating malignant tumors, which method comprises administering a [photokinetically treating] tumor detecting effective amount, to a host in need of [photokinetic treatment] tumor detection of a malignant tumor, of a compound or derivative thereof in which at least one carbon atom of 5-aminolevulinic acid is a carbon isotope and/or a nitrogen atom in its amino group is a nitrogen isotope, and where said derivative is an

AMENDMENT UNDER 37 C.F.R. § 1.116
U.S. Appln. No. 09/445,963

ester, amide, salt, hydrate or solvate of said compound[.]; detecting the malignant tumors using NMR; and selectively killing the malignant tumors.

11. (Amended) The method of claim 10 wherein said compound is used in combination with a diagnostically [or pharmaceutically] acceptable carrier.